

GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH  
MINISTRY OF HEALTH AND FAMILY WELFARE  
DIRECTORATE GENERAL OF DRUG ADMINISTRATION  
Mohakhali, Dhaka-1212  
www.dgda.gov.bd

**CERTIFICATE OF REGISTRATION**

We hereby declare that **Nimenrix powder and solvent for solution for injection in pre-filled syringe**, manufactured by **GlaxoSmithKline Biologicals S.A., Parc De La Noire Epine, Rue Fleming 20, 1300 Wavre, Belgium** (also responsible for quality control & primary packaging) for **Pfizer Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom**. Site responsible for batch release: **Pfizer Manufacturing Belgium NV, Rijksweg 12, B-2870 Puurs, Belgium** represented by **Radiant Export Import Enterprise, Lubdhok, 4<sup>th</sup> Floor, 474 P, Road No.-3, Sector-12, Uttara, Dhaka-1230, Bangladesh** is registered with Directorate General of Drug Administration & Licensing Authority (Drugs) under Registration Number **366-6324-018**..... The drug as described below is allowed to be imported into Bangladesh under **The Drugs Acts 1940 (XXIII of 1940) & The Drugs (Control) Ordinance, 1982, and its Amendment Act 2006**, subject to the provision of import policy published by the Government from time to time.

Name of Product : **Nimenrix**  
(Meningococcal group A, C, W-135 and Y conjugate vaccine)  
Dosage Form : Powder and solvent for solution for injection in pre-filled  
Pack size : 1 vial (0.5ml) with Lyophilised Vaccine + 1 pre-filled syringe with solvent

**Composition:**

**Active Ingredients**

Neisseria meningitidis group A polysaccharide<sup>1</sup>  
Neisseria meningitidis group C polysaccharide<sup>1</sup>  
Neisseria meningitidis group W-135 polysaccharide<sup>1</sup>  
Neisseria meningitidis group Y polysaccharide<sup>1</sup>

<sup>1</sup>Conjugated to tetanus toxoid carrier protein

**Other ingredient(s)**

**Powder:**

Trometamol

Sucrose

**Solvent:**

Sodium Chloride

Water for injections

**Specification**

P.Eur.  
P.Eur.  
P.Eur.  
P.Eur.

P.Eur.

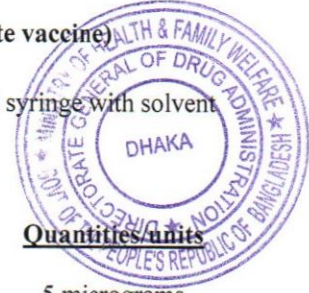
P.Eur.  
P.Eur.  
P.Eur.  
P.Eur.

**Quantities units**

5 micrograms  
5 micrograms  
5 micrograms  
5 micrograms

44 micrograms

97 micrograms  
28 milligrams  
4.5 milligrams  
q.s. ad 0.5 ml



**Instructions**  
To be dispensed only by or  
on the prescription of a  
registered physician.

**Conditions:**

1. Labelling should contain name and address of the Manufacturer, Batch number, Manufacturing date, Expiry date, M.R.P. (Maximum Retail Price), DAR No. (Drugs Administration Registration Number), (where applicable) etc. should be displayed on the label or container and also on the outer cover containing the container.
2. The registration will be valid for 5 (five) years from the date of issue unless it is revoked, suspended or cancelled earlier.
3. The certificate will be treated as cancelled in any violation of the conditions and the name or the formula of this product changed or modified qualitatively or quantitatively without due approval of the Licensing Authority.

Memo No. DA/15-5/13/366/ **24243** Dated. **08/11/2018**

c.c.to: M/s. Radiant Export Import Enterprise  
Lubdhok, 4<sup>th</sup> Floor, 474 P, Road No.-3,  
Sector-12, Uttara, Dhaka-1230

**Major General Md Mustafizur Rahman**  
Director General  
Directorate General of Drug Administration  
&  
Licensing Authority (Drugs) **NOV 2018**  
Government of the People's Republic of Bangladesh  
Ph. 880-2-9880803, email: dgda.gov@gmail.com

*Mohalabuddin*  
07.11.18

For Director General  
Directorate General of Drug Administration